

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

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**AFFYMETRIX, INC.**, a Delaware corporation,

Plaintiff/Counter-Defendant,

v.

**ILLUMINA, INC.**, a Delaware corporation,

Defendant/Counter-Plaintiff.

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) Civil Action No.: 04-901 JJF  
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**ILLUMINA'S MOTION TO VACATE AS A MATTER OF LAW THE JURY'S  
VERDICT OF INFRINGEMENT OF THE '716 PATENT UNDER THE DOCTRINE OF  
EQUIVALENTS ON THE BASIS OF PROSECUTION HISTORY ESTOPPEL**

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Dated: September 13, 2007

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## INTRODUCTION

The jury's finding of infringement of claims 1, 5 and 9 of U.S. Patent No. 5,795,716 ("the '716 patent") under the Doctrine of Equivalents must be vacated because the verdict is contrary to and inconsistent with Affymetrix's actions and admissions during prosecution of this patent. The verdict runs afoul of longstanding and controlling prosecution history estoppel precedent limiting the Doctrine's permissible reach, and thus cannot stand as a matter of law.

Prosecution history estoppel prevents patentees from reclaiming subject matter that was disclaimed, either expressly or impliedly, during the give-and-take process of obtaining a patent from the United States Patent and Trademark Office (PTO). Prosecution history estoppel can arise either through: (1) amendment-based estoppel, whereby a patentee is presumptively prevented from claiming equivalents on a limitation that was narrowed during prosecution in response to a rejection; or (2) argument-based estoppel, in which arguments made to the PTO effectively surrender coverage of the equivalent in question. In this case, Affymetrix's admissions during prosecution trigger both forms of estoppel. And each independently requires that the jury's verdict of infringement of the '716 patent solely under the Doctrine of Equivalents be vacated as a matter of law.

*First*, amendments made during prosecution of the '716 patent present a very clear-cut basis for a finding of amendment-based estoppel upon application of the basic rules set forth in *Festo Corporation v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722 (2002) ("*Festo VIII*") and its progeny. The specific limitation that Affymetrix argued and the jury found to be met by equivalents was added during prosecution to require that each claimed probe intensity "indicat[e] an extent of hybridization of a nucleic acid probe with at least one nucleic acid sequence including said sample sequence." Because this language was added in response to a rejection of the then-pending claims under both 35 U.S.C. § § 103 and 112, there can be no doubt

that the limitation was narrowed for a reason related to patentability, and the *Festo* analysis therefore applies.

Under the Supreme Court's decision in *Festo*, a presumption of estoppel arises because of Affymetrix's narrowing amendment. That presumption can be rebutted only if one of three narrowly-tailored exceptions apply: (1) "that the alleged equivalent would have been unforeseeable at the time of the narrowing amendment;" (2) "that the rationale underlying the narrowing amendment bore no more than a tangential relation to the equivalent in question;" or (3) "that there was 'some other reason' suggesting that the patentee could not reasonably have been expected to have described the alleged equivalent." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 344 F.3d 1359, 1368 (Fed. Cir. 2003) ("*Festo IX*") (citing *Festo VIII*, 535 U.S. at 740-41). As confirmed by Affymetrix's own arguments during the phase one trial, however, the alleged equivalent in question was known (and could have been claimed) prior to the filing or later amendment of the claims that ultimately issued in the '716 patent. Moreover, the precise language that was added during prosecution was at the heart of the equivalents finding by the jury and the arguments made by Affymetrix to allow the patent claims in the first place, and there is no basis for Affymetrix to now argue that the amendment was "merely tangential" to the adjudged equivalent. Thus, straightforward application of the amendment-based estoppel doctrine established by *Festo* precludes the jury's finding of infringement of the '716 patent under the Doctrine of Equivalents as a matter of law.

**Second**, in the alternative, the principles of argument-based estoppel also mandate that the finding of equivalents be vacated. Argument-based estoppel can be found where the patentee has clearly and unmistakably surrendered the adjudged equivalent in its communications with the PTO during prosecution. *Deering Precision Instruments, L.L.C. v. Vector Distrib. Sys., Inc.*,

347 F.3d 1314, 1326 (Fed. Cir. 2003). In this case, Affymetrix specifically distinguished prior art teaching the use of enzymes and tags to label and detect reactions between nucleic acids, arguing that such prior art was “[i]n stark contrast” to its invention involving the use of “probe intensities that indicate the extent of hybridization.” Because the Illumina products that were found to infringe employ the use of enzymes and tags for labeling and detection, Affymetrix’s admissions bar Affymetrix from now asserting that those claims cover the accused products.

Prosecution history estoppel keeps patentees such as Affymetrix from reclaiming subject matter that was expressly or impliedly disclaimed during the patenting process. *Festo VIII*, 535 U.S. at 734. Appreciating that the Doctrine of Equivalents can create “substantial uncertainty about where the patent monopoly ends,” the Supreme Court and Federal Circuit have used prosecution history estoppel to provide a check on the Doctrine so that competitors may rely on the public record of the patent proceedings. *Festo VIII*, 535 U.S. at 727, 730-734. Here, Affymetrix should not be able to recapture in litigation what it conceded during prosecution. *Id.* at 734. Application of controlling precedent, and the interests of justice, require that the jury’s finding of infringement of the ‘716 patent under the Doctrine of Equivalents be vacated as a matter of law.

### **NATURE AND STAGE OF THE PROCEEDINGS**

The Court conducted a jury trial in March 2007 on the “phase one” issues of infringement and damages. The jury found infringement of twelve claims from five patents that were asserted by Affymetrix, and awarded reasonable royalty damages totaling \$16,727,459. With respect to the ‘716 patent in particular, the jury found that Illumina’s products did not literally infringe asserted claims 1, 5 and 9, but did find these claims infringed under the Doctrine of Equivalents.

The other pending, although not fully briefed, motion before the Court is Affymetrix, Inc.’s Motion for Summary Adjudication on Illumina, Inc.’s Third and Seventh Affirmative

Defenses and Second Counterclaim (D.I. 272), relating to Affymetrix's assignor estoppel argument on the '716 patent defenses, which the Court indicated would be stayed until at least June 15, 2007. (D.I. 379) Related to this motion was Defendant Illumina, Inc.'s Motion to Dismiss Affymetrix's Count 2 for Lack of Standing and Subject Matter Jurisdiction, which the Court denied in an Order dated August 16, 2006, finding "that Dr. Robert Lipshutz conceived of the invention claimed in the '716 patent (the 'invention') sometime in the summer of 1992." (D.I. 326, 8/16/06 Memorandum Opinion, at 1.) On the basis of this ruling, it follows that Dr. Mark Chee was not an inventor on the asserted claims of the '716 patent (since the testimony of Drs. Chee and Lipshutz was that Chee only became involved with this work after Dr. Lipshutz's alleged conception date). Thus, Illumina believes that Affymetrix's assignor estoppel motion, which is premised on Dr. Chee being an inventor on the asserted claims, can and should be summarily denied without the need for full briefing.

The Court has set a status conference for October 10, 2007, and the parties have indicated their availability for the next phase(s) of trial during certain weeks in January and February 2008. Illumina believes that the instant motion should be ruled upon before any further issues are tried, because (if it is granted) the parties and Court could avoid the complication of including the '716 patent in the upcoming phases of the trial. Aside from this single discrete issue for the '716 patent, all other arguments for judgment as a matter of law arising from the phase one trial will be presented upon entry of judgment by the Court.

#### **FACTUAL BACKGROUND**

Affymetrix asserted at trial that Illumina infringed the '716 patent under the Doctrine of Equivalents based on alleged equivalence of a single limitation: "computer code that receives a plurality of signals corresponding to probe intensities for a plurality of nucleic acid probes, each probe intensity indicating an extent of hybridization of a nucleic acid probe with at least one



nucleic acid sequence including said sample sequence, and each nucleic acid probe differing from each other by at least a single base.” (See Trial Tr. (Guerra) at 809:14-810:17, 821:17-822:19; see also D.I. 383, Affymetrix’s Response To Illumina’s Motion *In Limine* #2 (setting forth this limitation as the only one for which Doctrine of Equivalents evidence would be presented)). This claim limitation was added through a narrowing amendment made during the prosecution history of the ‘716 patent to obtain its allowance, and was also the focus of admissions by Affymetrix to distinguish the prior art.

**A. The ‘716 Prosecution History.**

The application that led to the ‘716 patent was filed on October 21, 1994. (DTX 4 at IAFP189-240.) The claims of the original application related generally to computer programs or methods to assess data from experiments, with some claims requiring the experiments involve hybridization in some way, but with none of the claims specifically requiring assays in which probe intensities indicate the extent of hybridization. More particularly, none of the claims set forth in the original application, or in the preliminary amendment, contained the language “probe intensity *indicating an extent of hybridization* of a nucleic acid probe with at least one nucleic acid sequence including said sample sequence.” (*Id.* (emphasis added); DTX 4 at IAFP297-301.)

In a December 19, 1995 Office Action, the examiner rejected all claims under 35 U.S.C. § 112, second paragraph as indefinite. Specifically, the examiner explained his § 112 rejection as follows:

[I]t is not clear whether an “intensity” value is an intrinsic property of each individual probe or if the “intensity” is actually a reflection of the extent of hybridization of probe molecules at a specific site on the chip. The claim might be amended to clarify this point.

(DTX 4 at IAFP366.) These same claims were also rejected under 35 U.S.C. § 103 as being unpatentable over Fodor et al. (WO 92/10588) (“Fodor”), in view of Weiss et al. (U.S. Patent

No. 5,470,710) (“Weiss”), and Stockham et al. (U.S. Patent No. 5,273,632) (“Stockham”). (*Id.* at IAFP371-374.)

In response, on May 20, 1996, Affymetrix filed Amendment C canceling all claims and adding newly proposed claims 60-105.<sup>1</sup> (DTX 4 at IAFP390-408.) For the first time, the limitation “each probe intensity indicating an extent of hybridization of a nucleic acid probe...” was added to each independent claim.<sup>2</sup> (DTX 4 at IAFP390-397.) Affymetrix stated that claim 60 was “amended” to include this new limitation to overcome the examiner’s § 112 rejection:

In regard to claim 1, the Examiner stated that it is not clear how a probe intensity is associated with a nucleic acid probe. As the Examiner suggested, Applicants *amended* claim 60 to recite “each probe intensity indicat[es] an extent of hybridization of a nucleic acid probe with at least one nucleic acid sequence including said sample sequence.” Accordingly, the rejection does not apply to the new claims.

(DTX 4 at IAFP399 (emphasis added).)

Affymetrix also then went on to distinguish “amended claim 60” from the Weiss prior art on the basis of this additional language. More specifically, Affymetrix admitted that “Weiss describes utilizing an enzyme on identical probes that hybridize with tags,” but argued that the reference did not “disclose or suggest inputting probe intensities to identify an unknown base

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<sup>1</sup> Claim 60, DTX 4 at IAFP390 (“In a computer system, a method of identifying an unknown base in a sample nucleic acid sequence, said method comprising the steps of: inputting a plurality of probe intensities for a plurality of nucleic acid probes, *each probe intensity indicating an extent of hybridization of a nucleic acid probe with at least one nucleic acid sequence* including said sample sequence, and each nucleic acid probe differing from each other by a single base; said computer system comparing said plurality of probe intensities; and identifying said unknown base according to results of said comparing step.”) (emphasis added). See Exhibit 1, attached hereto, for a comparison of the prosecution history regarding issued claim 1 of the ‘716 patent and claims containing the same amended limitation.

<sup>2</sup> In conjunction with adding this limitation to the “inputting” step of “amended claim 60,” other language in the “comparing” step of the prior claims relating to probe intensities being “substantially proportional to said associated probe hybridizing with at least one nucleic acid sequence” was deleted. (DTX 4 at IAFP350, IAFP390-391.) This deleted language was also the subject of an indefiniteness rejection and request for clarification (DTX 4 at IAFP366), and was addressed by the inclusion of the narrowing “indicating an extent of hybridization” language in the amended claim (DTX 4 at IAFP399).

where the probe intensities indicate the extent of hybridization of probes differing by a single base and the sample nucleic acid sequence.” (DTX 4 at IAFP402.) Affymetrix concluded its arguments distinguishing Weiss and a related reference as follows:

*In stark contrast*, the present invention compares probe intensities that indicate the extent of hybridization of probes differing by a single base and the sample nucleic acid sequence.

(DTX 4 at IAFP403 (emphasis added).)

On January 13, 1997, and in response to a July 9, 1996 Office Action in which all pending claims were again rejected (albeit on different grounds), Affymetrix filed Amendment D. (DTX 4 at IAFP416-431.) Amendment D added proposed claims 106-117 (claims 108-117 correspond to issued claims 1-10 of the ‘716 patent).<sup>3</sup> (*Id.* at IAFP422-426.) Claims 1 and 5 of the ‘716 patent (issuing from application claims 108 and 112) contain the same amended language that was first presented in “amended claim 60” -- “each probe intensity indicating an extent of hybridization of a nucleic acid probe with at least one nucleic acid sequence including said sample sequence...” (*See* Ex. 1.) These claims were ultimately allowed on April 28, 1997 (DTX 4 at IAFP511-513), and the ‘716 patent issued on August 18, 1998 (DTX 3).

#### **B. Affymetrix’s Evidence Presented at Trial Regarding the Doctrine of Equivalents.**

The only evidence Affymetrix offered at trial on the Doctrine of Equivalents was two responses by Affymetrix’s expert Dr. Rudy Guerra explaining his opinion that Illumina’s use of enzymatic-based labeling and detection techniques was equivalent to the claimed techniques requiring a probe intensity indicating an extent of hybridization. For the analysis of Illumina’s Infinium I assay products, Dr. Guerra testified:

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<sup>3</sup> See Exhibit 1, attached hereto, for a comparison of the prosecution history regarding issued claim 1 and claims containing the same amended limitation.

Q: Have you also reached an opinion whether this claim element, this middle claim element is met under the Doctrine of Equivalents?

A: Yes.

Q: Could you describe your basis for that opinion?

A: Yes, I can. Why don't we go ahead and bring up 7.2, please. Okay. And so we have to recall here according to my understanding of the Doctrine of Equivalents is that we performed substantially the same function in substantially the same way to get substantially the same result, and that's exactly what is going on here. There might be some question as to whether the intensity that is read off from this particular probe A while the patient DNA is not hybridized at the time that the scanning is done, that really is irrelevant because the double-stranded hybrid is done at the probe location. The fact that it has been removed does not in any way affect the biotin labeling. It doesn't affect the fluorescent labeling and it doesn't affect the intensity reading, and so in the end, we end up getting an intensity reading by a labeled sample nucleic acid at a probe location.

(Trial Tr. (Guerra) at 809:14-810:17.) And Affymetrix's Doctrine of Equivalents evidence regarding Illumina's Golden Gate assay was limited to the following testimony by Dr. Guerra at trial:

Q: Have you also reached an opinion whether this claim element is met under the Doctrine of Equivalents?

A : Yes.

Q: Can you explain the basis for that opinion?

A: Sure. It's largely the same idea as before in that there might be some question as to this notion of hybridizing to a probe location. The hybridization actually occurs in solution as indicated by this day one workflow. And it's not until we get to the amplicon stage that these amplicons then get exposed to the array and then they go to the probe location.

However, as I said before, whether this particular patient DNA gets sent to the bead or not, it's not really relevant here because we have the amplicon which has that particular fragment, that black

part that is identical to the patient DNA, except it's just complementary.

So if I want to know about the signal intensity of the patient DNA at a particular location, that's the same as getting the intensity from the amplicon through the complimentary base rule.

(Trial Tr. (Guerra) at 821:17-822:19.)<sup>4</sup>

Affymetrix's counsel also argued that Illumina's products should be found to infringe by equivalents because, *inter alia*, enzymatic detection and labeling strategies like Illumina's were known prior to the filing of the application that led to the '716 patent. During Dr. Quackenbush's cross-examination, Affymetrix's counsel focused his attention on alternative labeling strategies known in the prior art and questioned Dr. Quackenbush regarding the W092/10588 published patent application (PTX 725), which is incorporated by reference in the '716 patent.<sup>5</sup> The questioning and later argument during closing define Affymetrix's position -- that enzymatic detection and labeling methods like those used in Illumina's assays were known prior to the filing of the '716 patent. (Trial Tr. (Quackenbush) at 1278:22-1279:9, 1279:17-1281:3; *see also* Trial Tr. (Affymetrix Closing) at 1721:22-1722:2.) Moreover, Affymetrix's expert Dr. Struhl testified that "[t]he properties of these enzymes [used in the Illumina assays]

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<sup>4</sup> Affymetrix's closing argument on how Illumina's products infringe under the Doctrine of Equivalents was: "So Dr. Guerra has concluded that this assay meets those middle elements literally. But what he says, that if you think this is a difference that is put on the probe and then it's washed away before it's detected, that's an insubstantial difference. So on this particular patent, you could find that under the doctrine of equivalents it has the same function, way and result, that it's an insubstantial difference, and that it is infringed under the doctrine of equivalents." (Trial Tr. (Affymetrix Closing) at 1615:23-1616:9); and "Dr. Guerra says I think this is literally infringing the '716 patent, this middle element. But if you conclude that there's a difference here, it's an insubstantial difference that works like any other microarray to pull a particular labeled fragment to a particular position, and be detected, and make a decision based on that." (Trial Tr. (Affymetrix Closing) at 1618:4-10).

<sup>5</sup> It is noteworthy that this same patent application (W092/10588) that formed the basis for Affymetrix's arguments of equivalents during the trial also formed the basis for the PTO's rejection of the claims prior to Affymetrix's narrowing amendment that is the subject of this motion. (*See, e.g.*, DTX 4 at IAFP 371-374.)

have been known for ages.” (Trial Tr. (Struhl) at 662:9-16.)<sup>6</sup> Despite the foreseeability of Illumina’s adjudged-equivalent assays “ages” before the ‘716 patent, or at least by the time of the prior art incorporated by reference in the ‘716 patent, Affymetrix did not literally claim this adjudged equivalent in the ‘716 patent. (Trial Tr. (Guerra) at 884:6-15.)

The jury found that Illumina’s genotyping products and assays did not literally infringe any of the asserted claims of the ‘716 patent, but did find these products and assays infringed under the Doctrine of Equivalents. (Trial Tr. at 1783:4-18.) Because of the admissions by Affymetrix during prosecution, and further confirmed during the recent trial, the finding of equivalents cannot stand as a matter of law.

### **ARGUMENT**

#### **A. Legal Standard for Motion to Vacate Jury Verdict for Legal Error.**

The Supreme Court has expressly stated that trial courts should enter judgment as a matter of law, and thus set aside a jury verdict, where a jury’s finding of infringement by equivalents is precluded by evidence establishing prosecution history estoppel. *Festo IX*, 344 F.3d at 1367-68. *See also, e.g., Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 39, n.8 (1997) (“Thus, under the particular facts of a case, if prosecution history estoppel would apply or if a theory of equivalence would entirely vitiate a particular claim element, partial or complete judgment should be rendered by the court, as there would be no further material issue for the jury to resolve.”). Whether prosecution history estoppel applies and whether the Doctrine of Equivalents may be available for a claim limitation are questions of law

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<sup>6</sup> Dr. Quackenbush further confirmed that an enzymatic-based approach similar to the method of Illumina’s Golden Gate assay was described in a prior art Ugozoli article dating back to 1991. (Trial Tr. (Quackenbush) at 1289:8-23.)

for the court.<sup>7</sup> *Festo IX*, 344 F.3d at 1368. *See also, e.g., Warner-Jenkinson Co., Inc.*, 520 U.S. at 39, n.8 (“the various legal limitations on the application of the doctrine of equivalents are to be determined by the court”).

**B. Amendment-Based Prosecution History Estoppel Mandates that the Court Vacate the Finding of Infringement Under the Doctrine of Equivalents.**

A jury verdict based on the Doctrine of Equivalents for a claim limitation that was narrowed for reasons of patentability during prosecution presents a clear-cut case of amendment-based prosecution history estoppel. Because the equivalent-in-question was, by Affymetrix’s own admissions, a foreseeable alternative to the alleged invention as literally claimed, *Festo* and its progeny mandate that the finding of equivalents must be vacated as a matter of law.

Recent case law from both the Supreme Court and the Federal Circuit has established relatively bright-line rules for determining when amendment-based prosecution history estoppel should be invoked. Where a claim limitation has been narrowed for a substantial reason relating to patentability, a presumption arises that the patentee has surrendered all subject matter between the original claim limitation and the amended claim limitation. *Festo VIII*, 535 U.S. at 740. The Federal Circuit has established that every narrowing amendment to address *any* rejection related to patentability, whether it be to address a prior art rejection or a deficiency under 35 U.S.C. § 112, triggers the presumption of estoppel. *Honeywell Int’l, Inc. v. Hamilton Sundstrand Corp.*, 370 F.3d 1131, 1142 (Fed. Cir. 2004) (“A patentee who narrows a claim as a condition for

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<sup>7</sup> The Court specifically excluded the issue of prosecution history estoppel from the phase one jury trial. (*See, e.g., Trial Tr.* at 1209:2-13.) Although Illumina has additional arguments as to why the equivalents verdict cannot stand with respect to the ‘716 patent, it intends to raise these other arguments (if necessary) at the same time it files its other JMOL arguments when judgment is entered by the Court. Illumina believes that this prosecution history estoppel issue for the ‘716 patent should be dealt with before the next phases of the trial -- so as to potentially streamline the issues that will be addressed in the remaining phases -- and believes that this legal issue can be resolved on the briefing given Affymetrix’s admissions during prosecution and the phase one trial.



obtaining a patent disavows his claim to the broader subject matter, whether the amendment was made to avoid the prior art or to comply with § 112.”).

Once the presumption of estoppel is established, “the patentee bears the burden of showing that a narrowing amendment did not surrender a particular equivalent and ... a patentee may rebut the presumption of surrender by showing that ‘at the time of the amendment one skilled in the art could not reasonably be expected to have drafted a claim that would have literally encompassed the alleged equivalent.’” *Festo IX*, 344 F.3d at 1368 (quoting *Festo VIII*, 535 U.S. at 741). The patentee may rebut the presumption of surrender by demonstrating: (1) “that the alleged equivalent would have been unforeseeable at the time of the narrowing amendment;” (2) “that the rationale underlying the narrowing amendment bore no more than a tangential relation to the equivalent in question;” or (3) “that there was ‘some other reason’ suggesting that the patentee could not reasonably have been expected to have described the alleged equivalent.” *Festo IX*, 344 F.3d at 1368 (citing *Festo VIII*, 535 U.S. at 740-41).

In this case, Affymetrix’s amendment of the limitation on which equivalents was found triggers a presumption of estoppel, and Affymetrix cannot meet its burden to establish any of the exceptions to rebut this presumption.

**1. Affymetrix’s narrowing amendment is a classic case in which estoppel is invoked.**

During the prosecution history of the ‘716 patent, Affymetrix amended the key claim limitation to avoid a prior art obviousness rejection and to comply with § 112, second paragraph. (DTX 4 at IAFP390-391, 398-399, 401-403.) A presumption of estoppel arises when an amendment adding a new claim limitation narrows the scope of the then-pending claims. *Honeywell Int’l Inc.*, 370 F.3d at 1141. Moreover, “a narrowing amendment made to comply with *any* provision of the Patent Act, including § 112, may invoke an estoppel.” *Festo IX*, 344



F.3d at 1366 (emphasis added). *See also, Biagro Western Sales, Inc. v. Grow More, Inc.*, 423 F.3d 1296, 1306 (Fed. Cir. 2005) (holding an amendment made to overcome a prior art obviousness rejection was a “narrowing amendment ... made for a reason substantially related to patentability”). There is no doubt that Affymetrix’s amendment adding the “indicating an extent of hybridization” language was both narrowing of the claims and made for a reason related to patentability.

During prosecution of the ‘716 patent, Affymetrix narrowed its original claims in its Amendment C filed May 20, 1996 by adding, *inter alia*, the claim limitation “each probe intensity indicating an extent of hybridization of a nucleic acid probe” to each of the independent claims, including application claim 60. (DTX 4 at IAFP390-97; *see also*, Ex. 1.) This amendment indisputably narrowed the claims -- there was nothing previously in the claims requiring the probe intensity *indicate an extent of hybridization*.<sup>8</sup> Moreover, there can be no dispute that this narrowing amendment was made for a reason related to patentability, as the language was added in the face of both § 112 indefiniteness and § 103 obviousness rejections.

It makes no difference that this amendment was made to an earlier progenitor claim as opposed to the specific claims that issued in the ‘716 patent. The Federal Circuit has repeatedly rejected such form-over-substance arguments in holding that “subject matter surrendered via claim amendments during prosecution is also relinquished for other claims containing the same limitation.” *Glaxo Wellcome, Inc. v. Impax Labs., Inc.*, 356 F.3d 1348, 1356 (Fed. Cir. 2004).<sup>9</sup>

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<sup>8</sup> As the evidence at trial indicated, intensities from nucleic acid experiments can indicate an extent of hybridization as required by the claims, or they can otherwise have some relationship to a hybridizing probe that is then the subject of an enzymatic reaction. (*See, e.g.*, Trial Tr. (Quackenbush) at 1226:6-1228:4.)

<sup>9</sup> *See also, Honeywell Int’l Inc.*, 370 F.3d at 1144 (“The scope of the patentee’s concession is determined on a limitation-by-limitation basis. *See Festo II [IX]*, 344 F.3d at 1367.”); *Ampex Corp. v. Eastman Kodak Co.*, 460 F.Supp.2d 563, 569 (D. Del. 2006) (“[A]ny subject matter surrendered via claim amendments during prosecution is also relinquished for other claims containing the same limitation.”).

Because the exact same language that was added to “amended claim 60” is also present in all of the claims found to be infringed under the Doctrine of Equivalents, the effect of this amendment in triggering a presumption of estoppel applies equally to these issued claims.<sup>10</sup> *Id.*

Affymetrix narrowed its claims in response to a rejection, and the presumption of estoppel is invoked. As a result, Affymetrix is estopped from asserting infringement based on equivalents of the narrowed claim, and the jury’s finding of infringement of the ‘716 patent under the Doctrine of Equivalents must be vacated.

## **2. Affymetrix cannot rebut the presumption of estoppel.**

Affymetrix cannot overcome the *Festo* presumption of prosecution history estoppel because (1) the alleged equivalent was foreseeable at the time the amendment was made as indicated through Affymetrix’s own statements during the prosecution history of the ‘716 patent and testimony at trial, (2) the alleged equivalent was not tangential to the purpose of the amendment, as the narrowing amendment was made to avoid prior art that contained the equivalent, and (3) there is no reason, *e.g.*, shortcomings of language, why Affymetrix was prevented from describing the alleged equivalent when the narrowing amendment was made. *Festo IX*, 344 F.3d at 1368. Based on the evidence presented *by Affymetrix* at the phase one trial, it can be concluded as a matter of law that none of these exceptions are possibly applicable.

The first exception requires Affymetrix to show that the alleged equivalent would have been unforeseeable to one of ordinary skill in the art at the time of the narrowing amendment. *Festo IX*, 344 F.3d at 1368. To the contrary, it is clear from the ‘716 patent and its prosecution history, as well as the statements made by Affymetrix’s counsel at trial, that the adjudged equivalent was known and thus foreseeable. (*See, e.g.*, DTX 3; PTX 725; Trial Tr.

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<sup>10</sup> See Ex. 1.

(Quackenbush) at 1278:22-1279:9, 1279:17-1281:3; Trial Tr. (Affymetrix Closing) at 1609:5-15.) Given this evidence and argument, Affymetrix cannot now argue that the alleged equivalent was unforeseeable. *Festo IX*, 344 F.3d at 1369 (“[I]f the alleged equivalent were known in the prior art in the field of the invention, it certainly should have been foreseeable at the time of the amendment.”). The facts presented at the phase one trial leave no doubt that the adjudged equivalent was foreseeable and could have been literally claimed, and therefore this first exception cannot save Affymetrix from estoppel.<sup>11</sup>

The second exception to the *Festo* presumption -- requiring Affymetrix to show the rationale underlying the amendment bore no more than a tangential relation to the alleged equivalent -- also does not apply. It is well-established that “an amendment made to avoid prior art that contains the equivalent in question is *not* tangential; it is central to allowance of the claim.” *Festo IX*, 344 F.3d at 1369 (emphasis added). The prosecution history clearly shows that the amendment in response to the § 112 rejection was made not only as an effort to clarify the claim limitation, but to also overcome a prior art obviousness rejection. (DTX 4 at IAFP366, 371-374, 399, 401-403.) Because the amendment was made in part to distinguish prior art relating to enzymes and tags -- as confirmed by the arguments focusing on this distinction -- it is anything but tangential to the adjudged equivalent. See *Biagro Western Sales, Inc.*, 423 F.3d at 1306 (holding patentee “cannot claim that the rationale for the amendment is merely tangential”

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<sup>11</sup> Affymetrix cannot now argue that the alleged equivalent was unforeseeable when the evidence of record at trial clearly established it was known. See *Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 480 F.3d 1335, 1343 (Fed. Cir. 2007) (holding patentees argument that the alleged equivalent was unforeseeable was contrary to “the evidence of record clearly demonstrat[ing] that the use of an undercut or recess, the alleged equivalent here, is an old and well known fundamental of basic machining and was entirely foreseeable at the time of the amendment to one of ordinary skill in the art.”); *Ranbaxy Pharms., Inc. v. Apotex, Inc.*, 350 F.3d 1235, 1241 (Fed. Cir. 2003) (“[T]he notion that acetic acid was unforeseeable at the time of application flies in the face of the fact that Apotex stated that formic acid and acetic acid, as homologs, are readily known by chemists to exhibit similar properties and are therefore equivalent.”).

when the reason for the amendment and the accused equivalent in the case both relate to same issue).

The third exception also provides Affymetrix no salvation. This exception requires Affymetrix to establish “some other reason,” such as shortcomings of language, why Affymetrix was unable to describe the alleged equivalent at the time of the narrowing amendment. *Festo IX*, 344 F.3d at 1370. Once again, the fact that Affymetrix has admitted that the adjudged equivalent was known in the art is fatal to any argument that this third exception applies. *Festo IX*, 344 F.3d at 1370 (“a patentee may not rely on the third rebuttal criterion if the alleged equivalent is in the prior art, for then ‘there can be no other reason the patentee could not have described the substitute in question.’”) (quoting *Pioneer Magnetics, Inc. v. Micro Linear Corp.*, 330 F.3d 1352, 1357 (Fed. Cir. 2003)). There was “no linguistic or ‘other’ limitation” preventing Affymetrix from describing the adjudged equivalent in its claims, and the prosecution history suggests Affymetrix chose not to do so because assays involving enzymes were not part of its claimed invention.<sup>12</sup> *Festo IX*, 344 F.3d at 1372.

Affymetrix simply cannot rebut the presumption of amendment-based prosecution history estoppel created by its narrowing amendment of the ‘716 patent claims. The verdict of infringement under the Doctrine of Equivalents must be vacated because it conflicts with the well-established case law governing amendment-based estoppel.

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<sup>12</sup> At trial, Affymetrix submitted evidence that Affymetrix’s products use enzymes. (*See, e.g.*, Trial Tr. (Fodor) at 289:11-290:8, 384:6-17; Trial Tr. (Barker) at 1132:6-1134:8; Trial Tr. (Affymetrix Closing) at 1721:4-1722:17.)

**C. Argument-Based Prosecution History Estoppel Also Bars Affymetrix from Recapturing Under the Doctrine of Equivalents Subject Matter that it Surrendered During Prosecution.**

As an independent and alternative ground in support of this motion, the principles of argument-based prosecution history estoppel also dictate that the finding of infringement by equivalents of the '716 patent cannot stand. "To invoke argument-based estoppel, the prosecution history must evince a clear and unmistakable surrender of subject matter." *Deering Precision Instruments, L.L.C.*, 347 F.3d at 1326. Contrary to amendment-based estoppel, the court "do[es] not presume a patentee's arguments to surrender an entire field of equivalents through simple arguments and explanations to the patent examiner." *Conoco, Inc. v. Energy & Envtl. Int'l, L.C.*, 460 F.3d 1349, 1364 (Fed. Cir. 2006). Instead, the relevant inquiry becomes "whether a competitor would reasonably believe that the applicant had surrendered the relevant subject matter." *Id.*

Affymetrix's statements to the PTO during prosecution of the '716 patent could hardly be more "clear and unmistakable" that Affymetrix was surrendering the alleged equivalent (*i.e.*, use of enzymes and/or tags for labeling and detection, instead of simply hybridization of a labeled probe to generate a probe intensity). (*See, e.g.*, Trial Tr. (Quackenbush) at 1247:24-1248:20.) During prosecution, Affymetrix specifically distinguished prior art teaching the use of enzymes and tags to label and detect reactions between nucleic acids. (DTX 4 at IAFP402-403.) Affymetrix stated to the PTO, "[m]ore specifically, Weiss describes utilizing an *enzyme* on identical probes that hybridize with *tags* in the fragments of the nucleic acid ladder." (DTX 4 at IAFP402 (emphasis added); Trial Tr. (Guerra) at 876:8-14); Trial Tr. (Quackenbush) at 1245:10-1246:4.) Affymetrix explained that "Weiss and Stockham do not disclose or suggest inputting probe intensities to identify an unknown base where the probe intensities indicate the extent of hybridization of probes differing by a single base and the sample nucleic acid sequence." (DTX

4 at IAFP402; Trial Tr. (Quackenbush) at 1246:5-18.) And then Affymetrix went so far as to say that Weiss and Stockham are “*in stark contrast*” to Affymetrix’s invention that “compares probe intensities that indicate the extent of hybridization.”<sup>13</sup> (DTX 4 at IAFP403; Trial Tr. (Guerra) at 876:15-24; Trial Tr. (Quackenbush) at 1246:19-1247:18.).

Because Illumina’s products that were found to infringe by equivalents employ the use of enzymes and/or tags for labeling and detection, argument-based estoppel also dictates that the finding of equivalents be vacated. *See, e.g., Seachange Int’l, Inc. v. C-COR, Inc.*, 413 F.3d 1361, 1372-73 (Fed. Cir. 2005) (“Where an applicant argues that a claim possesses a feature that the prior art does not possess in order to overcome a prior art rejection, the argument may serve to narrow the scope of otherwise broad claim language.”); *Springs Window Fashions LP v. Novo Indus., L.P.*, 323 F.3d 989, 994 (Fed. Cir. 2003) (holding “it is clear that the applicant disclaimed coverage of Novo’s [defendant’s] device” when applicant amended claims to include the word “separate” to distinguish prior art that was “nearly identical” to defendant’s device). Because a patent and its prosecution history serve a public notice function, any ambiguities should be resolved against Affymetrix. *See, e.g., Springs Window Fashions LP*, 323 F.3d at 995 (“The public notice function of a patent and its prosecution history requires that a patentee be held to what he declares during the prosecution of his patent ... ‘The prosecution history constitutes a public record of the patentee’s representations concerning the scope and the meaning of the claims, and competitors are entitled to rely on those representations when ascertaining the degree of lawful conduct ... Were we to accept [the patentee’s] position, we would undercut the public’s

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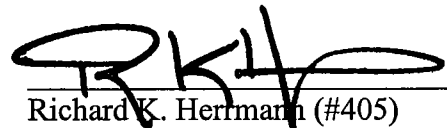
<sup>13</sup> Affymetrix added the limitation “each probe intensity indicating an extent of hybridization of a nucleic acid probe” in its May 20, 1996 Amendment C in response to the examiner’s rejections under § 103 and § 112, second paragraph. *See* Ex. 1. Similar to the discussion above for amendment-based estoppel, Affymetrix is estopped from equivalents in claims 1, 5 and 9 because the limitation on which the argument-based estoppel is based is found in these claims. *Eagle Comtronics, Inc. v. Arrow Comm. Labs., Inc.*, 305 F.3d 1303, 1316 (Fed. Cir. 2002) (“Any argument-based estoppel affecting a limitation in one claim extends to all claims in which that limitation appears.”).

reliance on a statement that was in the public record and upon which reasonable competitors formed their business strategies.’”) (quoting *Hockerson-Halberstadt, Inc. v. Avia Group Int’l, Inc.*, 222 F.3d 951, 957 (Fed. Cir. 2000)). Argument-based estoppel bars Affymetrix’s application of the Doctrine of Equivalents because Affymetrix clearly and unmistakably relinquished the coverage of assays using enzymes and tags during prosecution of the ‘716 patent.

### CONCLUSION

For the foregoing reasons, Illumina respectfully requests that this Court grant its Motion to Vacate the Jury’s Verdict of Infringement of the ‘716 Patent as A Matter of Law and find that Affymetrix is estopped from asserting the Doctrine of Equivalents.

Dated: September 13, 2007



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